



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Rimed Ltd.
% Ms. Ahava Stein
Regulatory Consultant
20 Hata'as St. (POB 124)
Kfar Saba 44425
ISRAEL

June 23, 2015

Re: K143476
Trade/Device Name: Digi-One System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, ITX
Dated: May 22, 2015
Received: May 28, 2015

Dear Ms. Stein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Robert A. Ochs". The signature is written in a cursive style. In the background, there is a faint, large, light gray watermark of the letters "FDA".

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K143476

Device Name
Digi-One System

Indications for Use (Describe)

The Digi-One System is indicated for non-invasive evaluation of intracranial and extracranial vascular flow velocity irregularities in adult and in children. It is not intended for fetal use. It is not intended for neonatal use.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Indications for Use Form
Fill out one form for each ultrasound system and each transducer.

Digi-One System:

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	C	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic				X	X					
Fetal										
Abdominal										
Intra-operative (Specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic				X						
Cardiac										
Trans-esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular				X	X					
Laparoscopic										
Musculo-Skeletal Conventional										
Musculo-Skeletal Superficial										
Other (Specify)										

Additional Comments:

Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

1 MHZ PW HAND-HELD TRANSDUCER

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	C	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-operative (Specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic				X						
Cardiac										
Trans-esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular				X						
Laparoscopic										
Musculo-Skeletal Conventional										
Musculo-Skeletal Superficial										
Other (Specify)										

Additional Comments:

Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

2 MHZ PW HAND-HELD TRANSDUCER

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	C	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic				X						
Fetal										
Abdominal										
Intra-operative (Specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic				X						
Cardiac										
Trans-esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular				X						
Laparoscopic										
Musculo-Skeletal Conventional										
Musculo-Skeletal Superficial										
Other (Specify)										

Additional Comments:

Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

4 MHZ TRANSDUCER

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	C	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-operative (Specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular				X	X					
Laparoscopic										
Musculo-Skeletal Conventional										
Musculo-Skeletal Superficial										
Other (Specify)										

Additional Comments:

Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

8 MHZ TRANSDUCER

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	C	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-operative (Specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular				X	X					
Laparoscopic										
Musculo-Skeletal Conventional										
Musculo-Skeletal Superficial										
Other (Specify)										

Additional Comments:

SUMMARY OF SAFETY AND EFFECTIVENESS

K143476

(Premarket Notification [510(k)] Number)

1. Submitter Information

Manufacturer Name and Address

Rimed Ltd.
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PO Box 2402
Industrial Park Raanana 4365613,
Israel

Official Correspondent

Ahava Stein
A. Stein – Regulatory Affairs Consulting Ltd.
20 Hata'as St. (Beit Hapaamon, Suite 102)
Kfar Saba 44425,
Israel

2. Date Prepared: May 18, 2015

3. Device Name Digi-One System

Proprietary Name: Digi-One System

Common Name: Transcranial Doppler (TCD) Device

FDA Classification Name: 21 CFR 892.1550; Ultrasonic Pulsed Doppler Imaging System

FDA Classification: Class II, Product Code IYN; ITX

4. Predicate Devices

The Digi-One System is substantially equivalent to the following devices:

Manufacturer	Device	510(k)	Date Cleared
Rimed Ltd.	Digi-Lite System	K062578	August 23, 2006

5. Device Description

The Digi-One System is a small, lightweight, portable digital Transcranial Doppler (TCD) system with an advanced M-mode display which can be connected to any external Windows based PC.

It measures the blood flow velocity in the main cerebral arteries non-invasively for circulation diagnosis and HITS (High Intensity Transient Signals) detection using the same Rimed TCD software application as the predicate device.

The Digi-One System is a modification of the Digi-Lite System. The hardware was modified using current electronic components, and the software was modified to allow installation on a dedicated PC (such as a laptop device). Otherwise, the functionality of the system remains identical to that of the Digi-Lite system in all aspects, including acoustic power outputs, clinical parameter measurement accuracy, examination modes, available transducers, software menus and commands (with some minor user interface modifications). As the specifications remain identical, the safety and efficacy of the device are not affected when used as labeled. Therefore, the Digi-One system remains substantially equivalent to the predicate, un-modified Digi-Lite System.

Predicate Comparison Table:

Technological Characteristic	Digi-One System Rimed Ltd.	Digi-Lite System Rimed Ltd. (K062578)
Product Code, Class	IYN, ITX Class II	IYN, ITX Class II
Indications for Use	The Digi-One System is indicated for non-invasive evaluation of intracranial and extracranial vascular flow velocity irregularities in adults and in children. It is not intended for fetal use. It is not intended for neonatal use.	The Digi-Lite System is indicated for non-invasive evaluation of intracranial and extracranial vascular flow velocity irregularities in adults and in children. It is not intended for fetal use. It is not intended for neonatal use.
Energy Used / Delivered	Ultrasound energy	Ultrasound energy
Design: (Modification from predicate)	The Digi-One System consists of a small unit which connects to a PC and to which probes are connected.	The Digi-Lite System consists of a unit with a display to which probes are connected.
- Mechanism of Action	Doppler Ultrasound, with the following modes: Unilateral Bilateral Multichannel Monitoring Multidepth (up to 8 spectrums at various depths) M-Mode (64 gates)	Doppler Ultrasound, with the following modes: Unilateral Bilateral Multifrequency Multichannel Monitoring Multidepth (up to 8 spectrums at various depths) M-Mode (64 gates)

Technological Characteristic	Digi-One System Rimed Ltd.	Digi-Lite System Rimed Ltd. (K062578)
- Accessories	Probe types: - 1MHz PW, 16mm - 2MHz PW, 14mm - 4MHz PW/CW, 8mm - 8MHz PW/CW, 5mm Remote control Monitoring probe holder Color printer Footswitch	Probe types: - 1MHz PW, 16mm - 2MHz PW, 14mm - 4MHz PW/CW, 8mm - 8MHz PW/CW, 5mm Remote control Monitoring probe holder Color printer Footswitch CD ROM backup DAT Tape
Performance <u>Sample volume</u> Depth Power (%)	(for 1 MHz) (for 2 MHz) 15-92 mm 15-146 mm 0-100% at 7% steps	(for 1 MHz) (for 2 MHz) 15-92 mm 15-146 mm 0-100% at 7% steps
Acoustic output	1MHz PW Ispta=34.15mW/cm ² 2MHz PW Ispta=181.3mW/cm ² 4MHz PW Ispta=232.2mW/cm ² 4MHz CW Ispta=183mW/cm ² 8MHz PW Ispta=149.8mW/cm ² 8MHz CW Ispta=414mW/cm ²	1MHz PW Ispta=34.15mW/cm ² 2MHz PW Ispta=181.3mW/cm ² 4MHz PW Ispta=232.2mW/cm ² 4MHz CW Ispta=183mW/cm ² 8MHz PW Ispta=149.8mW/cm ² 8MHz CW Ispta=414mW/cm ²

6. Indications for Use

The Digi-One System is indicated for non-invasive evaluation of intracranial and extracranial vascular flow velocity irregularities in adults and in children. It is not intended for fetal use. It is not intended for neonatal use.

7. Performance Standards

There are no performance standards under the Federal Food, Drug and Cosmetic Act, for the Digi-One System.

8. Performance Testing

The following Software and Performance tests were performed on the Digi-One System:

- Software Validation according to FDA Guidelines (tested modified software)
- Bench testing to validate output energies and parameter calculation accuracies
- Electrical and Mechanical Safety Standard (IEC 60601-1)
- Electromagnetic Compatibility Standard (IEC60601-1-2)

9. Technological Characteristics Compared to Predicate Device

The original Digi-Lite device underwent modification to electronics and software. The safety and effectiveness questions that were raised by these changes were

equivalence of acoustic power outputs, equivalence of measurement accuracy, and safe use under low-power modes. Performance testing of the modified device included measurements of output power and measurement accuracy. The testing results demonstrated that the modified device is substantially equivalent to the predicate, unmodified device. The software functions and testing modes did not change, except for some User Interface improvements; the system defaults for low-power modes were reviewed for equivalence to the predicate device, and were demonstrated to remain identical. Software testing was performed on the modified software. The technological characteristics, e.g., overall design, materials, mechanism of action, mode of operation, performance characteristics, etc., and the indications for use of the modified Digi-One System are substantially equivalent to the predicate device cited above. Based on the results of performance testing, the Digi-One device is substantially equivalent to the predicate device.